

**STATEMENT OF KAREN M. HICKS, Ph.D.**  
**Dalkon Shield Survivor and Founder, DSIN, Inc.**

Summary

Like almost 4 million other women, I, too, trusted the safety assurances of the A. H. Robins Company, manufacturer of the Dalkon Shield IUD, which claimed this product was the "Cadillac of Contraception" in the early 1970s. My doctor trusted the company's literature and convinced me that it would improve the quality of my life. But we were all horribly deceived by both the Shield's inventor, who falsified his research data and lied under oath to a Congressional committee about his personal financial stake in the product, and by Robins, which rushed this product to market in order to gain a competitive edge over rival IUD makers.

The Dalkon Shield IUD caused untold misery to hundreds of thousands of its users. The leading cause of the injuries has been attributed to the multifilament tailstring, which, unlike previous IUDs, allowed bacteria to climb up into the uterus, in a wicking effect. This tailstring was manufactured by a different company in Germany. Company officials continued to deny its responsibility for causing this senseless and cruel tragedy. The Dalkon Shield Claimants Trust, which was set up in 1990, as a result of the A. H. Robins bankruptcy litigation, is a pitiful substitute for civil justice. The settlement offer that I and thousands of other women received only added insult to injury. Sadly, these types of global, capped funds are proliferating and threaten to limit the right of average citizens to gain access to the courts for remedies to torts.

My heart goes out to persons who face life-threatening or debilitating illnesses and must make a difficult decision about implanting medical devices in their bodies. Relative to my experience, I think that these people are more intensely vulnerable to risky products and negligent companies. What guarantees do we have that all the risks will be disclosed to us? In these cases, more protection against unethical businesses, not less, is crucial.

Have such cases of egregious misconduct diminished? I think not. The situation has probably grown worse. The news accounts that I read now demonstrate familiar and dishonorable corporate tactics. Shredded documents, denial of accountability, and blaming the victims for their misfortunes prevails. Relaxing existing laws will not improve the health and well being of Americans. Product liability laws should continue to be guided by principles which protect the interests of consumers who trust medical devices to do no harm.

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**Dalkon Shield Survivor and Founder, DSIN, Inc.**

Like almost 4 million other women, I, too, trusted the safety assurances of the A. H. Robins Company, manufacturer of the Dalkon Shield IUD, which claimed this product was the "Cadillac of Contraception" in the early 1970s. My doctor trusted the company's literature and convinced me that it would improve the quality of my life. But we were all horribly deceived by both the Shield's inventor, who falsified his research data and lied under oath to a Congressional committee about his personal financial stake in the product, and by Robins, which rushed this product to market in order to gain a competitive edge over rival IUD makers.

The Dalkon Shield IUD caused untold misery to hundreds of thousands of its users, resulting in perforated uteri, an epidemic of pelvic inflammatory disease, infertility, infected miscarriages, ectopic pregnancies, and even deaths.

Before Robins withdrew it from the market, U.S. District Court Judge Miles Lord, of Minnesota, called it a ticking time bomb in women's wombs.

The leading cause of the injuries has been attributed to the multifilament tailstring, which, unlike previous IUDs, allowed bacteria to climb up into the uterus, via a wicking effect. This tailstring was manufactured by a different company in Germany. One of the quality control supervisors at Robins tried to tell top corporate officials that this could be a problem. They fired him.

I began using the Dalkon Shield in 1971. Over the next 10 years, I suffered many medical problems. However, the Robins Company had skillfully and deliberately suppressed the facts about the havoc it was wrecking on women's bodies.

Neither I nor my doctors were able to pinpoint the cause of my damage for more than a decade. In 1984, one week after I was married, I had to have an emergency total hysterectomy from the cumulative damages I had suffered for so long. That time bomb finally exploded and robbed me of my fertility, at the age of 36. For all those years, I was told that my problems were "all in my head." The emotional wreckage is too painful to talk about.

It's been more than 25 years since my first injuries. I brought a claim against the Robins Company in 1984, and shortly thereafter this company hid behind the shield of the

bankruptcy laws to protect its assets. Company officials continued to deny its responsibility for causing this senseless and cruel tragedy.

The Dalkon Shield Claimants Trust, which was set up in 1990, as a result of the bankruptcy litigation, is a pitiful substitute for civil justice. The settlement offer that I and thousands of other women received only added insult to injury. Sadly, these types of global, capped funds are proliferating and threaten to limit the right of average citizens to gain access to the courts for remedies to torts.

My heart goes out to persons who face life-threatening or debilitating illnesses and must make a difficult decision about implanting medical devices in their bodies. Relative to my experience, I think that people in this situation are more intensely vulnerable to risky products and negligent companies. What guarantees do we have that all the risks will be disclosed to us? I don't mean to trivialize my experience, but I wasn't in a health crisis at the time that I made the decision to use the Dalkon Shield. In these cases, more protection against unethical businesses, not less, is crucial.

One suggestion that I have made elsewhere is to call for the establishment of a nationwide, comprehensive registry system for all medical devices and pharmaceutical products.

If it is possible to develop a computerized system for registering car parts and recalling defective toaster ovens, we can certainly offer medical consumers greater guarantees against harm through a program of notification and corrective action for drugs and devices. Such a system would provide a huge database that could also be used to construct the proper and necessary studies related to long-term use, improve the problem of inadequate follow-up, and allow for early warnings that would diminish bad outcomes. Honest, ethical companies would be only too eager to comply with the public's need to know and to be fully informed.

I learned many hard lessons from the Dalkon Shield case. It has made me pessimistic and cynical about the bottom line mentalities as the guiding beacon for business in this country. I wonder what lessons the corporations learned from this case. Have business ethics improved? Have cases of egregious misconduct diminished? I think not. The situation has probably even deteriorated. One current example comes to mind. The Reynolds tobacco company is located in Richmond, Virginia, which is the hometown of the A. H. Robins Company. The news accounts that I read now demonstrate familiar and dishonorable corporate tactics. Shredded documents, denial of accountability, and blaming the victims for their misfortunes prevails. Relaxing existing laws will not improve the health and well being of Americans. Product liability laws should continue to be guided by the interests of consumers who trust medical devices to do no harm.

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**EDUCATION**

1990	<b>Ph.D.</b>	University of Pennsylvania Educational Leadership, Graduate School of Education
1983	<b>M.A.</b>	Lehigh University Social Relations, Focus: Anthropology
1973	<b>M.A.</b>	University of Massachusetts Education, Focus: Reading Education
1968	<b>B.A.</b>	Michigan State University Spanish Education
1964	<b>High School Diploma</b>	Balboa High School Balboa, Panama Canal Zone

**PROFESSIONAL EMPLOYMENT**

1996-Present	<b>Coordinator, Women's Studies Coalition and Consortial Professors Program</b>	Lehigh Valley Association of Independent Colleges, Inc.
1994-1996	<b>Associate Dean for Student Life</b>	Albright College, Reading, PA
1990-1994	<b>Director, Women's Center and Assistant Professor, Psychology</b>	Albright College, Reading, PA
1984-1989	<b>Visiting Lecturer,</b>	Department of Social Relations Lehigh University, Bethlehem, PA
1983-1986	<b>Administrative Associate,</b>	Emulsion Polymers Institute Lehigh University, Bethlehem, PA
1980-1983	<b>Teaching Assistant,</b>	Social Relations Lehigh University, Bethlehem, PA
1968-1979	<b>Public School Teacher</b>	(Spanish, Bilingual Education, and Remedial Reading) Various school districts in Michigan, Massachusetts, and Pennsylvania